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Notice of Independent Review Decision

Date notice sent to all parties:

October 15, 2015

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

L4-S1 Mini 360 Fusion - 2 Day inpatient stay

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:

MD, Board Certified Orthopedic Surgeon

REVIEW OUTCOME:

Upon independent review, the reviewer finds that the previous adverse determination/adverse determinations should be:

☒ Upheld (Agree)

Provide a description of the review outcome that clearly states whether medical necessity exists for each of the health care services in dispute.

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient is a female who reported an injury to her low back. The clinical note dated xxxxxx indicates the patient had been xxxxxxxx resulting in a sharp pain near her tailbone. The patient reported no numbness or weakness in the lower extremities at that time. Range of motion testing was identified as painful, specifically with extension and side bending. The MRI of the lumbar spine dated 03/06/14 revealed a central disc protrusion at L4-5 measuring 2.4mm. Cord compression and canal stenosis was identified. Bilateral facet hypertrophy was also identified. Right sided foraminal stenosis was present. A slight spur and disc bulge formation was identified at L5-S1. Facet arthropathy and canal narrowing was also identified. The clinical note dated 04/30/15 indicates the patient continuing with low

back pain. The patient was identified as having normal sensation in the lower extremities. The patient reported axial low back pain. However, the patient also reported bilateral leg pain which appeared to be worsening at that time. There is an indication the patient had been recommended for injection therapy at that time. The clinical note dated 05/15/15 indicates the patient continuing with low back pain with radiating pain to both buttocks and posterior thighs. The note indicates the patient utilizing Neurontin at that time for pain relief. The patient was recommended for an epidural steroid injection at the L4-5 level. The operative note dated 05/28/15 indicates the patient undergoing an L4-5 epidural steroid injection. The clinical note dated 06/25/15 indicates the patient continuing with low back pain with radiating pain to both lower extremities. The patient reported a 2 week relief of pain following the epidural injection. However, the patient reported a return to baseline levels of pain. The patient was subsequently recommended for an L4-5 and L5-S1 fusion.

The utilization reviews dated 07/29/15 and 09/04/15 resulted in denials as insufficient information had been submitted confirming the likely benefit of the proposed L4-5 and L5-S1 fusion.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS, AND CONCLUSIONS USED TO SUPPORT THE DECISION:

The documentation indicates the patient complaining of ongoing low back pain. The patient has been recommended for an L4 through S1 mini 360 fusion. A fusion surgery in the lumbar region is indicated for patients with confirmatory evidence in place in the form of imaging studies regarding findings consistent with spondylolisthesis, a herniation with significant radiculopathy, or a surgical intervention consistent with the need for a revision. The submitted MRI revealed mild narrowing at the L4-5 level. A disc bulge was also identified at L5-S1. However, no findings consistent with a spondylolisthesis or findings consistent with symptomatic radiculopathy were identified. The clinical notes indicate the patient showing no neurologic involvement in the appropriate distributions. No nerve root compression was identified in the imaging studies. Furthermore, no information was submitted regarding the patient's instability at the appropriate levels confirmed by x-rays. Given the lack of objective evidence confirmed by clinical exam and taking into account the minimal findings identified on the MRI, the request is not supported. Given the non-certification of the surgery, the additional request for a 2 day inpatient stay is rendered non-certified as well. As such, it is the opinion of this reviewer that the request for an L4 through S1 mini 360 fusion with a 2 day inpatient stay is not recommended as medically necessary.

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:

☒ **MEDICAL JUDGEMENT, CLINICAL EXPERIENCE, AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS**

☒ **ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES**

Fusion (spinal)v

Patient Selection Criteria for Lumbar Spinal Fusion:

(A) Recommended as an option for the following conditions with ongoing symptoms, corroborating physical findings and imaging, and after failure of non-operative treatment (unless contraindicated e.g. acute traumatic unstable fracture, dislocation, spinal cord injury) subject to criteria below:

- (1) Spondylolisthesis (isthmic or degenerative) with at least one of these:
 - (a) instability, and/or
 - (b) symptomatic radiculopathy, and/or
 - (c) symptomatic spinal stenosis;
- (2) Disc herniation with symptomatic radiculopathy undergoing a third decompression at the same level;
- (3) Revision of pseudoarthrosis (single revision attempt);
- (4) Unstable fracture;
- (5) Dislocation;
- (6) Acute spinal cord injury (SCI) with post-traumatic instability;
- (7) Spinal infections with resultant instability;
- (8) Scoliosis with progressive pain, cardiopulmonary or neurologic symptoms, and structural deformity;
- (9) Scheuermann's kyphosis;
- (10) Tumors.

(B) Not recommended in workers' compensation patients for the following conditions:

- (1) Degenerative disc disease (DDD);
- (2) Disc herniation;
- (3) Spinal stenosis without degenerative spondylolisthesis or instability;
- (4) Nonspecific low back pain.

(C) Instability criteria: Segmental Instability (objectively demonstrable) - Excessive motion, as in isthmic or degenerative spondylolisthesis, surgically induced segmental instability and mechanical intervertebral collapse of the motion segment and advanced degenerative changes after surgical discectomy, with relative angular motion greater than 15 degrees L1-2 through L3-4, 20 degrees L4-5, 25 degrees L5-S1. Spinal instability criteria includes lumbar inter-segmental translational movement

of more than 4.5 mm. (Andersson, 2000) (Luers, 2007) (Rondinelli, 2008)

(D) After failure of two discectomies on the same disc [(A)(2) above], fusion may be an option at the time of the third discectomy, which should also meet the ODG criteria. (See ODG Indications for Surgery -- Discectomy.)

(E) Revision Surgery for failed previous fusion at the same disc level [(A)(3) above] if there are ongoing symptoms and functional limitations that have not responded to non-operative care; there is imaging confirmation of pseudoarthrosis and/or hardware breakage/malposition; and significant functional gains are reasonably expected. Revision surgery for purposes of pain relief must be approached with extreme caution due to the less than 50% success rate reported in medical literature. Workers compensation and opioid use may be associated with failure to achieve minimum clinically important difference after revision for pseudoarthrosis (Djurasovic, 2011) There is low probability of significant clinical improvement from a second revision at the same fusion level(s), and therefore multiple revision surgeries at the same level(s) are not supported.

(F) Pre-operative clinical surgical indications for spinal fusion should include all of the following:

(1) All physical medicine and manual therapy interventions are completed with documentation of reasonable patient participation with rehabilitation efforts including skilled therapy visits, and performance of home exercise program during and after formal therapy. Physical medicine and manual therapy interventions should include cognitive behavioral advice (e.g. ordinary activities are not harmful to the back, patients should remain active, etc.);

(2) X-rays demonstrating spinal instability and/or myelogram, CT-myelogram, or MRI demonstrating nerve root impingement correlated with symptoms and exam findings;

(3) Spine fusion to be performed at one or two levels;

(4) Psychosocial screen with confounding issues addressed; the evaluating mental health professional should document the presence and/or absence of identified psychological barriers that are known to preclude post-operative recovery;

(5) For any potential fusion surgery, it is recommended that the injured worker refrain from smoking for at least six weeks prior to surgery and during the period of fusion healing; (Colorado, 2001) (BlueCross BlueShield, 2002)

(6) There should be documentation that the surgeon has discussed potential alternatives, benefits and risks of fusion with the patient;

(7) For average hospital LOS after criteria are met, see Hospital length of stay (LOS).